IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	))))	C.A. No. 05-356-KAJ (consolidated)

NOTICE OF DEPOSITION UNDER FED. R. CIV. P. 30(b)(6) TO TEVA PHARMACEUTICALS INDUSTRIES, LTD. AND TEVA PHARMACEUTICALS USA

PLEASE TAKE NOTICE that on March 21, 2006 commencing at 9:00 a.m., at the offices of Covington & Burling, 1201 Pennsylvania Avenue, N.W., Washington, D.C. 20004, Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P. and Synaptech, Inc. (collectively, "Plaintiffs" or "Janssen") will take the deposition upon oral examination of Defendants Teva Pharmaceuticals Industries, Ltd. and Teva Pharmaceuticals USA (collectively, "Teva") pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure. This deposition upon oral examination will be conducted before an officer authorized to administer oaths and will be recorded by stenographic and videographic means.

Plaintiffs serve this Notice without waiver of its objections to the deficiencies in Teva's document production and other discovery responses concerning the subject matter of the instant Notice, and reserve the right to continue this deposition as necessary in light of any subsequent document production by Teva.

Plaintiffs will take this deposition upon oral examination through one or more officers, directors, managing agents or other persons designated by Teva pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure as the person(s) knowledgeable to testify on Teva's behalf concerning the topics identified in Schedule A. Teva is requested to provide counsel for Plaintiffs with the identity of the individual(s) who will testify regarding each

topic at least one week in advance of the deposition. The deposition will continue from day to day until completed with such adjournments as to time and place as may be necessary. You are invited to attend and examine the witness(es).

ASHBY & GEDDES

/s/ Lauren E. Maguire

Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
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Dated: February 21, 2006
166731.1

SCHEDULE A

Definitions

1. As used herein, "Teva" shall mean Defendants Teva Pharmaceuticasl Industries, Ltd. and Teva Pharmaceuticals USA and all of Teva's corporate parents, corporate predecessors and past or present subsidiaries, affiliates, divisions, departments, officers, directors, principals, agents and employees.

2. As used herein, "Teva's ANDA" shall mean Teva's Abbreviated New Drug Application Number 77-587.

3. As used herein, "the Generic Product" shall mean the proposed generic galantamine product that is the subject of Teva's ANDA 77-587.

4. As used herein, "the '318 patent" shall mean United States Patent No. 4,663,318.

5. As used herein, "document" shall have the full meaning ascribed to it by the Federal Rules of Civil Procedure and shall include any means for retaining information.

6. As used herein, "FDA" shall mean the United States Food and Drug Administration.

7. As used herein, "Paragraph IV notice" refers to Teva's April 22, 2005 letter to Plaintiffs attached hereto as Exhibit 1.

8. "Person" and "persons" mean any natural person and any business, legal, corporate, or governmental entity, association, or organization.

9. "Alzheimer's Disease" means any diagnosis, illness, or ailment described as being of the Alzheimer's type, including without limitation Senile Dementia of the Alzheimer's Type, and/or Alzheimer's Dementia.

10. "Galantamine" includes without limitation galantamine, galanthamine, and any salt of galatamine, such as galantamine hydrobromide.

11. "Rasagiline" refers to Teva's irreversible monoamine oxidase type-B inhibitor promoted and/or marketed under the name Agilect in the USA and Azilect in Europe.

Topics of Examination

1. Teva's Paragraph IV notice including, without limitation, the meaning of, basis for, and any evaluation or analysis concerning the statement set forth in the letter that "Claims 1, 4 and 5 of the '318 patent are invalid under 35 U.S.C. § 103 because they are obvious in view of the … prior art ."

2. Teva's Paragraph IV notice including, without limitation, the meaning of, basis for, and any evaluation or analysis concerning the statement set forth in the letter that "the Bhasker Article renders claims 1, 4 and 5 of the '318 patent are invalid under 35 U.S.C. § 103 because they are would have been obvious to one of ordinary skill in the art at the time of the invention."

3. Teva's Paragraph IV notice including, without limitation, the meaning of, basis for, and any evaluation or analysis concerning the statement set forth in the letter that "claim 1 … is invalid under 35 U.S.C. § 102(b) as anticipated by P.A. Bhasker, *Medical Management of Dementia*."

4. The circumstances under which Teva first became aware of the P.A. Bhasker article cited in Teva's Paragraph IV notice, *Medical Management of Dementia*, including how Teva learned of it, who was involved in this first awareness, and any evaluation conducted of it by or on behalf of Teva, then or subsequent to the time Teva became aware of it.

5. Any evaluation, consideration or discussion conducted by Teva to market or develop the Generic Product, including the names and responsibilities of all persons

who were involved in the evaluation, consideration or discussion by Teva to market or develop the Generic Product.

6. The decision to file an application with the FDA seeking approval to manufacture and sell a drug product containing galantamine.

7. The benefits, including revenues and profits, that Teva projects, anticipates, expects, or forecasts it will obtain should Teva's ANDA receive approval from the U.S. Food and Drug Administration.

8. Marketing strategies, marketing plans, and projected sales for Teva's Generic Product.

9. The names and responsibilities of all persons who were involved in any evaluation, consideration or discussion to license or market Rasagiline as a treatment for Alzheimer's Disease conducted by or on behalf of Teva.

10. Marketing strategies, marketing plans, and projected sales for Rasagiline as a treatment for Alzheimer's Disease.

11. Each and every contribution and/or input that Teva, or any employee or agent of Teva, has made to the preparation, decision to file, filing and/or prosecution of Teva's ANDA, including: (a) any information relating to regulatory procedures and strategies for obtaining regulatory approval of the Generic Product of Teva's ANDA; (b) any information comprising, relating to or contained in the 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certifications submitted in connection with Teva's ANDA; and (c) any information comprising, relating to or contained in the statements of factual and legal basis for invalidity, unenforceability, and/or noninfringement included with the notice of these certifications.

12. The factual basis for Teva's proposed assertion that Teva's ANDA is indicated for the treatment of mild to moderate Alzheimer's disease.

13. The circumstances in which Teva first became aware of galantamine as a treatment for Alzheimer's disease, including but not limited to the date on which this occurred and the people involved.

14. The circumstances in which Teva first became aware of the '318 patent, including but not limited to the date on which this occurred and the people involved.

15. Any consideration or evaluation taken by Teva to develop a drug product containing galantamine for the treatment of Alzheimer's Disease.

16. Identification of all individuals, whether employees of Teva or third parties, having a role in the consideration or evaluation by Teva of developing a drug product containing galantamine for the treatment of Alzheimer's disease that is the subject of Topic 15.

17. Any consideration or evaluation by Teva of licensing the '318 patent.

18. Identification of all individuals, whether employees of Teva or third parties, having a role in the consideration or evaluation by Teva of licensing the '318 patent that is the subject of Topic 17.

19. Any effort by Teva to develop any drug product other than the Generic Product set forth in Teva's ANDA.

20. Identification of all individuals, whether employees of Teva or third parties, having a role in the research, development or testing of such a treatment responsive to Topic 18 and a description of those roles.

21. The circumstances surrounding Teva's first decision that Rasagiline could be used to treat Alzheimer's Disease and any analysis or evaluation for treating Alzheimer's Disease.

22. Any evaluation, investigation, or analysis suggesting that Rasagiline is not useful as a treatment for Alzheimer's Disease.

23. Teva's decision to evaluate, analyze, or investigate cholinesterase inhibitor derivatives, including but not limited to TV3326 and TV3279.

24. Teva's efforts to obtain any regulatory approval from any authority to use Rasagiline or any derivative of it as a treatment of Alzheimer's Disease, including without limitation whether Teva has obtained or failed to obtain such approval.

25. The factual and legal bases for Teva's statement that each claim of the '318 patent is invalid for failure to satisfy one or more of sections 101, 102, 103, 112, and 116 of Title 35 of the United States Code (Second Defense).

26. The factual and legal bases for Teva's Second Claim for Relief (declaratory judgment of invalidity) according to its proof elements, including an element-by-element comparison of each asserted claim of the '318 patent to the prior art Teva relies upon and the motivation of one of skill in the art to combine any references under 35 U.S.C. §103, as well as a description of any non-prior art defenses such as lack of enablement, insufficient written description, failure to disclose best mode, or claim indefiniteness under 35 U.S.C. § 112.

27. The identity and location of documents and things concerning the foregoing topics.

28. Teva's document retention policies from 1986 to the present.

29. Persons knowledgeable about the subject matter of the foregoing topics.

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EXHIBIT 1

Administrative Offices:
TEVA PHARMACEUTICALS USA
1090 Horsham Road, PO Box 1090
North Wales, PA 19454-1090

Phone: (215) 591 3000
FAX: (215) 591 8600

CONFIDENTIAL
April 22, 2005

VIA FEDERAL EXPRESS DELIVERY:

Janssen Pharmaceutica Products, L.P.
Corporation Trust Company
820 Bear Tavern Road
Trenton, NJ 08628

Janssen Pharmaceutica Products, L.P.
1125 Trenton Harbourton Rd
Titusville, New Jersey 08560

Janssen Pharmaceutica N.V.
30 Turnhoutseweg
Beerse, B 2340 Belgium

Synaptech, Inc.
C/O Schwartz & Salomon, P.C.
ATT: Joseph Salomon
225 Broadway, S-1515
New York, NY 10007

RE: Patent Certification Notice- U.S. Patents Nos. 4663318, 6099863 and 6358527
Galantamine Hydrobromide Tablets, Eq. 4 mg base, 8 mg base and 12 mg base
Teva Pharmaceuticals USA, Inc.'s, ANDA 77-587

Dear President and/or Counsel:

Pursuant to 21 U.S.C. § 355(j)(2)(B) and Section 505(j)(2)(B)(ii) of the Food and Drug Act, Teva Pharmaceuticals USA, Inc. ("Teva USA"), a Delaware corporation with a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454, hereby gives notice that Teva USA has submitted an Abbreviated New Drug Application 77-587 ("ANDA 77-587") for Teva USA's Galantamine Hydrobromide Tablets, Eq. 4 mg base, 8 mg base and 12 mg base ("Teva's Galantamine Tablets"), containing a Paragraph IV Certification (pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)) with respect to U.S. Patent Nos. 4,663,318 ("the '318 patent"), 6,099,863 ("the '863 patent"), and 6,358,527 ("the '527 patent"), which are listed in FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations*. ANDA 77-587 was submitted to obtain approval to engage in the commercial manufacture, use, or sale of Teva's Galantamine Tablets before the expiration of these patents, and contains data from bioavailability or bioequivalence studies.

A detailed statement of the factual and legal bases of Teva USA's opinion regarding the invalidity, unenforceability or noninfringement of the claims of the '318, '863 and '527 patents is enclosed. Teva USA reserves the right to develop additional grounds, reasons, or authorities that any or all of the claims of these patents are invalid or not infringed, and/or that these patents are unenforceable.

An Offer of Confidential Access to Teva USA's ANDA 77-587, pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), accompanies this notice as a separate enclosure.

Sincerely,

Paul H. Fackler, Ph.D.
Vice President, Research & Development

Enclosures: Teva Pharmaceuticals USA, Inc.'s Detailed Statement Of The Factual And Legal Bases That U.S. Patent Nos. 4663318, 6099863 and 6358527 Are Invalid, Unenforceable Or Not Infringed

Teva Pharmaceuticals USA, Inc.'s Offer of Confidential Access to ANDA 77-587.

ABBREVIATED NEW DRUG APPLICATION 77-587
OFFER OF CONFIDENTIAL ACCESS
PURSUANT TO 21 U.S.C. § 355(j)(5)(C)(i)(III)

WHEREAS Teva Pharmaceuticals USA, Inc. ("Teva") has provided notice to Janssen Pharmaceutica N.V., Janssen Pharmaceutica Products, L.P. and Synaptech, Inc. (hereinafter "Recipients"), that Teva submitted to the U.S. Food and Drug Administration ("FDA") Abbreviated New Drug Application 77-587 for Galantamine Hydrobromide Tablets, Eq. 4 mg base, 8 mg base and 12 mg base (referred to hereinafter in whole or in part as the "ANDA"), containing a Paragraph IV certification with respect to U.S. Patents 4,663,318, 6,099,863 and 6,358,527 (the "Listed Patents"), which are listed in the FDA Publication, "Approved Drug Products with Therapeutic Equivalence Evaluations"; and

WHEREAS this document constitutes Teva's Offer of Confidential Access to that ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) which provides:

> The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement;

and

WHEREAS Teva desires to offer to provide Recipients confidential access to the ANDA subject to restrictions as to persons entitled access to, and on the use and disposition of, the ANDA; and

WHEREAS this document accompanies Teva's Notice and Detailed Statement under 21 U.S.C. § 355(j)(2)(B) with respect to the Listed Patents;

NOW, THEREFORE:

1. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), and subject to the restrictions contained in Section 2 below, Teva hereby provides Recipients this Offer of Confidential Access ("Offer") for the sole purpose of determining whether to bring an action referred to in 21 U.S.C. § 355(j)(5)(B)(iii) with respect to the Listed Patents.

2. This Offer is subject to the following restrictions as to persons entitled to access and the use and disposition of any information accessed:

A. **Persons Entitled to Access:** Persons entitled to access ("Authorized Evaluators") under this Offer of Confidential Access are restricted to: (i) outside counsel engaged or employed by Recipients to represent them and the staff of such outside counsel, including paralegal, secretarial and clerical personnel who are engaged in assisting such counsel, provided that such outside counsel has been identified to Teva in writing; (ii) no more than two (2) in-house counsel and the staff of such in-house counsel, including paralegal, secretarial and clerical personnel who are engaged in assisting such counsel; and (iii) independent consultants and experts assisting in the evaluation of possible infringement of the Listed Patents and any employees and assistants under the control of such consultant or expert.

B. **Materials Accessible by Authorized Evaluators:** A copy of the ANDA, redacted to remove information of no relevance to any issue of patent infringement, will be provided for use by Authorized Evaluators.

C. **Use of the ANDA and Information in the ANDA:**

(1) The ANDA and all information contained therein or derived therefrom may be used for the sole and limited purpose of evaluating possible infringement of the Listed Patents and for no other purpose.

(2) Authorized Evaluators shall not disclose any information contained in or derived from the ANDA or any notes, analyses, studies or other documents to the extent that they reflect any information in the ANDA, to any person other than person entitled to access under subsection A.

(3) Notwithstanding the provisions of subsections 2(C)(1) and 2(C)(2) above, Authorized Evaluators shall be permitted to advise Recipients whether or not to bring suit alleging infringement of the Listed Patents; provided, however, that the information in the ANDA is not thereby disclosed.

D. **Disposition of the Information in the ANDA:**

(1) Recipients agree that if they do not file suit against Teva alleging infringement of the Listed Patents within forty-five (45) days of receipt of the Notice and Detailed Statement (the "45-day period"), which this offer accompanies, Recipients shall cause Authorized Evaluators within thirty (30) days after the expiration of the 45-day period, to destroy or return to Teva the portions of the ANDA provided, and all notes, analyses, studies or other documents to the extent that they contain information in the ANDA, and Recipients shall notify Teva that this has been done.

(2) Recipients agree that if Recipients file suit against Teva alleging infringement of the Listed Patents within the 45-day period:

(a) While the litigation is pending, the portions of the ANDA provided and all notes, analyses, studies or other documents to the

extent that they contain information in the ANDA, shall be treated as information under the highest level of confidentiality under any protective order entered in the action brought against Teva. Until such a protective order is entered, subsection 2(C)(2) above continues to apply.

(b) Recipients shall cause Authorized Evaluators to destroy or return to Teva the portions of the ANDA provided and all notes, analyses, studies or other documents prepared to the extent that they contain information in the ANDA, within thirty (30) days after the final determination of the action brought against Teva.

(3) Notwithstanding the provisions of subsections 2(D)(1) and 2(D)(2) above, each outside law firm authorized to have access pursuant to subsection 2(A)(i) shall be permitted to retain one copy of the portions of the ANDA provided and each note, analysis, study or other document to the extent that they contain information in the ANDA.

E. **Accidental Disclosure**: Should information contained in the ANDA be disclosed, inadvertently or otherwise, Recipients shall, at their earliest opportunity, by and through Authorized Evaluators, contact Teva and identify:

(1) what has been disclosed;

(2) the individuals to whom such information has been disclosed; and

(3) steps taken by Recipients and Authorized Evaluators to ensure the information in the ANDA is not further disseminated.

3. Recipients acknowledge that violation of any provision of this Offer will cause irreparable injury to Teva, and that an adequate legal remedy does not exist. Teva, therefore, shall have the right, in addition to any other remedies available at law or in equity, to obtain from a court of competent jurisdiction an injunction to prohibit Recipients from violating the terms of this Offer. Recipients agree that in such an action Teva is entitled to recover any and all damages, costs and expenses, including, but not limited to, all reasonable attorneys' fees, professional fees and court costs.

4. Should any provision set forth in this Offer be found by a court of competent jurisdiction to be illegal, unconstitutional or unenforceable, the remaining provisions shall continue in full force and effect.

5. Nothing contained herein shall be construed as a grant of any license or other right to use the information in the ANDA except for the purpose expressly stated herein.

6. When accepted by Recipients, this document shall constitute the entire agreement of the parties with respect to the subject matter herein and may not be amended or modified except in writing executed by all of the parties.

7. Recipients may request access to the ANDA by executing one copy of this Offer where indicated and returning the executed copy to Paul H. Fackler within the 45-day

Confidential: Teva Pharmaceuticals USA, Inc.'s Detailed Statement Of The Factual And Legal Bases That U.S. Patent Nos. 4,663,318, 6,099,863 and 6,358,527 Are Invalid, Unenforceable, Or Not Infringed.

This is the detailed statement of Teva Pharmaceuticals USA, Inc. ("Teva USA"), pursuant to Section 505(j)(2)(B)(ii) of the Food and Drug Act (codified at 21 U.S.C. § 355(j)(2)(B)(ii), and 21 C.F.R. § 314.95(c)), of the factual and legal bases of Teva USA's opinion that U.S. Patent Nos. 4,663,318 ("the '318 patent"), 6,099,863 ("the '863 patent") and 6,358,527 ("the '527 patent") are invalid, unenforceable or will not be infringed, either literally or under the doctrine of equivalents, by the commercial manufacture, use, or sale of Teva USA's Galantamine Hydrobromide Tablets, Eq. 4 mg base, 8 mg base and 12 mg base ("Teva's Galantamine Tablets") before the expiration of the '318, '863 and '527 patents. Teva USA's factual and legal bases are set forth below.

I. U.S. PATENT NO. 4,663,318

The '318 patent, entitled "Method of Treating Alzheimer's Disease", issued on 5 May 1987 from Application No. 819,141, filed on 15 January 1986. The patent is assigned to Synaptech, Inc.

The '318 patent contains 7 claims, of which claim 1 is the sole independent claim and recites a method of treating Alzheimer's disease and related dementias by administering galantamine or a pharmaceutically-acceptable acid addition salt thereof. Claim 1 is reproduced below:

> 1. A method of treating Alzheimer's disease and related dementias which comprises administering to a patient suffering from such a disease a therapeutically effective amount of galanthamine or a pharmaceutically-acceptable acid addition salt thereof.

Claims 2–7 ultimately depend on claim 1 providing further limitations such as dosages and methods of administration.

II. U.S. PATENT NO. 6,099,863

The '863 patent, entitled "Fast-Dissolving Galanthamine Hydrobromide Tablet", issued on 8 August 2000 from Application No. 09/202,187, filed on 6 June 1997 as PCT Application No. PCT/EP97/02986. Priority is claimed from European Patent No. 96201676, filed on 14 June 1996. The patent is assigned on its face to Janssen Pharmaceutica N.V., Beerse, Belgium.

The '863 patent contains 10 claims, of which claim 1 is the sole independent claim and recites a tablet containing galantamine hydrobromide. Claim 1 is reproduced below:

> 1. A tablet comprising as an active ingredient a therapeutically effective amount of galanthamine hydrobromide (1:1) and a pharmaceutically acceptable carrier, wherein said carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.

Claims 2–9 ultimately depend on claim 1 providing further limitations such as composition and weight percentages of the component compounds of the tablet. Claim 10 is directed to a process of preparing a tablet according to claim 3.

III. U.S. PATENT NO. 6,358,527

The '527 patent, entitled "Fast-Dissolving Galanthamine Hydrobromide Tablet", issued on 19 March 2002 from Application No. 09/585,122, filed on 1 June 2000. This application is a continuation of Application No. 09/202,187, filed as Application No. PCT/EP97/02986 on 6 June 1997, which is now U.S. Pat. No. 6,099,863. Priority is claimed from European Patent No. 96201676, filed on 14 June 1996. It is assigned on its face to Janssen Pharmaceutica N.V., Beerse, Belgium.

The '527 patent contains 6 claims, of which claims 1 and 6 are independent. Independent claim 1 and claims 2–5 are drawn to a method of treating a disorder selected from dementia, mania or nicotine dependence by administering a tablet containing galantamine hydrobromide.

Independent claims 1 recites:

> 1. A method of treating a disorder selected from dementia, mania or nicotine dependence in a patient in need thereof comprising administering to the patient a tablet comprising as an active ingredient a therapeutically effective amount of galanthamine hydrobromide (1:1) and a pharmaceutically acceptable carrier, wherein said carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.

Claim 2 limits the disorder to dementia and claim 3 limits dementia to Alzheimer's dementia. Claims 4 and 5 ultimately depend upon claim 1, providing further limitations regarding disorders.

Claim 6 is drawn to a fast-dissolving galanthamine hydrobromide tablet and is reproduced below:

> 6. A fast-dissolving galanthamine hydrobromide (1:1) tablet made by (i) dry blending the active ingredient, an insoluble or poorly soluble cross-linked polymer disintegrant and an optional glidant with a diluent comprising a spray dried mixture of lactose monohydrate and microcrystalline cellulose (75:25); (ii) optionally mixing a lubricant with the mixture obtained in step (i); (iii) compressing the mixture obtained in step (i) or in step (ii) in the dry state into a tablet; and (iv) optionally film-coating the tablet obtained in step (iii).

IV. LEGAL PRINCIPLES

A. Non-Infringement

A person is a direct infringer under 35 U.S.C. § 271(a) if that person makes, uses, sells or offers to sell in the United State, or imports into the United States, any patented invention without authorization of the patent holder. Direct infringement may be either literal or under the doctrine of the equivalents.

1. Literal Infringement

A patent claim is literally infringed if every limitation found in a properly interpreted claim is present in the accused product or process. *Markman v. Westview Instruments*, 53 F.3d 967, 979 (Fed. Cir. 1995) (*in banc*), *aff'd*, 517 U.S. 370, 116 S. Ct. 1384 (1996); *Lantech, Inc. v. Keip Mach. Co.*, 32 F.3d 542, 547 (Fed. Cir. 1994); *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 532 (Fed. Cir. 1996), *cert. denied* 65 U.S.L.W. 3799 (1997). Literal infringement requires the presence of each and every claim element. *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760 (Fed. Cir. 1983).

"One who does not infringe an independent claim cannot infringe a claim dependent on (and thus concerning all the limitations of) that claim." *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989).

2. Infringement Under The Doctrine Of Equivalents

Where literal infringement is not present, infringement under the doctrine of equivalents may be found where the "accused product or process contains elements identical or equivalent to each claimed element of the patented invention." *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 117 S.Ct. 1040, 1054 (1997). The determination of equivalents should be applied as an objective inquiry on an element-by-element basis. *Id.* at 1049. The Supreme Court has left it to the Federal Circuit to refine the formulation of the test for equivalents on a case-by-case basis.[1]

Infringement under the doctrine of equivalents requires the presence of each and every claim element, or the equivalent. *Unique Concepts Inc. v. Brown*, 19 USPQ2d 1500 (Fed. Cir. 1991).

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[1] In *Hilton Davis Chemical Co. v. Warner-Jenkinson Co.* 62 F.3d 1512, 1518 (Fed. Cir. 1995) *(in banc) rev 'd on other grounds* 41 USPQ2d 1865 (S. Ct. 1997), the Federal Circuit held "that application under the doctrine of equivalents rests on the substantiality of the differences between the claimed and accused products or processes, assessed according to an objective standard. One way of determining "substantiality" under the doctrine of equivalents, is if "the accused product or process performs substantially the same function, in substantially the same way, to achieve substantially the same result as the claims." *See also Goodwall Constr. Co. v. Beers Constr. Co.*, 991 F.2d 751, 757-58 (Fed. Cir. 1993) (citing *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950)).

> "[T]he limits of a patent must be known for the protection of the patentee, the encouragement of the inventive genius of others and the assurance that the subject of the patent will be dedicated ultimately to the public." Otherwise, a "zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention only a little less than unequivocal foreclosure of the field," and "[t]he public [would] be deprived of rights supposed to belong to it, without being clearly told what it is that limits these rights."

Markman v. Westview Instruments, Inc., 116 S. Ct. 1384, 1396 (1996) (citations omitted).

"[T]he concept of equivalency cannot embrace a structure that is specifically excluded from the scope of the claims." *Dolly, Inc. v. Spalding & Evenflo Cos.*, 16 F.3d 394, 400 (Fed. Cir. 1994).

The doctrine of equivalents cannot be used to erase "meaningful structural and functional limitations of the claim on which the public is entitled to rely in avoiding infringement." *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 935 (Fed. Cir. 1987) (*in banc*), *cert. denied*, 485 U.S. 1009 (1988) (quoting *Perkin-Elmer Corp. v. Westinghouse Elec. Corp.*, 822 F.2d 1528, 1532 (Fed. Cir. 1987)); *see also Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608, *reh'g denied*, 340 U.S. 845 (1950) (doctrine of equivalents inapplicable in the case of a substantial change between limitation recited in claim and corresponding element in accused product). The doctrine of equivalents cannot be employed in a manner that wholly vitiates a claim limitation. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29-30 (1997).

Subject matter disclosed in the specification but not claimed is dedicated to the public, and cannot be recaptured under the doctrine of equivalents. *Johnson & Johnston Associates, Inc. v. R.E. Service Co.*, 62 USPQ2d 1225 (Fed. Cir. 2002); *Maxwell v. Baker, Inc.*, 86 F.3d 1098 (Fed. Cir. 1996).

Subject matter in the prior art to a patent cannot infringe the claims of that patent either literally or under the doctrine of equivalents. *Lewmaar Marine, Inc. v. Bariant, Inc.*, 827 F.2d 744 (Fed. Cir. 1987) ("that which would literally infringe later in time anticipates if earlier than the date of invention"); *Insta-Foam Prods. v. Universal Foam Sys.*, 906 F.2d 698 (Fed. Cir. 1990) ("the doctrine of equivalents cannot . . . be used by a patentee to extend the right to exclude others so broadly as to ensnare subject matter within the public domain").

The doctrine of equivalents is limited by the scope of the prior art. It is axiomatic that the scope of patent claims cannot be expanded under the doctrine of equivalents to cover subject matter in or obvious in view of the prior art. *Wilson Sporting Goods Co. v. David Geoffrey &*

Assocs., 904 F.2d 677, 684 (Fed. Cir. 1990), *cert. denied*, 498 U.S. 992 (1990).[2] Moreover, the patentee cannot "cut and trim, expanding here, and narrowing there, to arrive at a claim that encompasses an accused device, but avoids the prior art." *Streamfeeder LLC v. Sure-Feed Inc.*, 175 F.3d 974 (Fed. Cir. 1999).

The doctrine of equivalents is limited by the doctrine of prosecution history estoppel. Prosecution history (or "file wrapper") estoppel limits the scope of claims by excluding the patentee from recapturing subject matter presumed to be surrendered during prosecution of the patent. *South Wall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d, 1570, 1579 (Fed. Cir. 1995); *Townsend Eng'g Co. v. Hitec Co., Ltd.*, 829 F.2d 1086, 1090 (Fed. Cir. 1987). A patentee can overcome a presumption of surrender of equivalents by: 1) showing that the equivalent in question was unforeseeable at the time the narrowing amendment was made (unforeseeability); 2) demonstrating that the narrowing amendment bore only a tangential relationship to the equivalent in question (tangential relationship) or 3) providing some other reason that prevented the claims from encompassing the equivalent in question during prosecution. *Festo Co. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359 (Fed. Cir. 2003).

3. Determination Of Infringement

The patent owner has the burden of proving by a preponderance of the evidence that "every limitation of the patent claim asserted to be infringed is found in the accused [product], either literally or by an equivalent." *Smithkline Diag., Inc. v. Helena Lab. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988), *aff'd*, 926 F.2d 1161 (Fed. Cir. 1991). Determination of infringement, either literally or under the doctrine of equivalents, is a question of fact. *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998).

To determine whether a product infringes a United States patent, there is a two-step inquiry in which the court: (1) construes the claim; and (2) compares the properly construed claim to the accused device or process. *Markman*, 52 F.3d at 976.

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[2] *Wilson Sporting Goods* sets forth a test for determining whether expansion of a claim to cover an accused product is legitimate. A hypothetical claim is created which covers the accused product. If that claim covers or is obvious in view of the prior art, it is impermissibly broad, and there is no infringement under the doctrine of equivalents. The patentee bears the burden of proving that the hypothetical claim does not cover the prior art. It may not redraft its claim by broadening it to cover the accused product while narrowing it to avoid the prior art. A hypothetical claim analysis is not an opportunity to freely redraft granted claims. That opportunity existed in the PTO, where the submitted claims were examined for patentability. Other statutorily prescribed procedures exist for post-grant modification of claims in the PTO in appropriate circumstances. *** While use of a hypothetical claim may permit a minor extension of a claim to cover subject matter that is substantially equivalent to that literally claimed one cannot, in the course of litigation and outside of the PTO, cut and trim, expanding here, and narrowing there, to arrive at a claim that encompasses an accused device, but avoids the prior art. Slight broadening is permitted at that point, but not narrowing. *** Wholesale redrafting of granted claims during litigation by narrowing and expanding the claims at the same time in creating a hypothetical claim is not supported by our case law and it avoids the examination process. *** Hypothetical claim analysis thus cannot be used to redraft granted claims in litigation by narrowing and broadening a claim at the same time. *Streamfeeder LLC v. Sure-Feed Inc.*, 175 F.3d 974, 983 (Fed. Cit. 1999).

When construing a claim the courts should rely on the claim language, the specification, the prosecution history and, if necessary to aid the court's understanding of the patent, extrinsic evidence. *See Elekta Instrument S.A. v. O.U.R. Scientific Int'l*, Inc., 214 F.3d 1302 (Fed. Cir. 2000); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1500 (Fed. Cir. 1998).

B. Invalidity

1. Anticipation

A claimed invention is invalid as anticipated if it was described in a patent or printed publication either before the date of invention by the applicant or more than one year before the filing date of the application. 35 U.S.C. §§ 102(a), (b), A patent or printed publication anticipates a claimed invention if it expressly describes the claimed invention, or if the claimed invention is necessarily inherent in the patent or printed disclosure. *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342, 1346-47 (Fed. Cir. 1999); *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987).

2. Obviousness

A claim is invalid as obvious if the differences between the subject matter sought to be patented and the prior are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. § 103. This inquiry is a question of law based on factual inquiries. *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17-18 (1966).

A claim may be proven obvious in view of a single prior art reference or in view of a combination of prior art references. When prior art references are combined to invalidate a claim under 35 U.S.C. § 103, some teaching, suggestion or motivation to combine the references must exist that is found in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). An absolute prospect for success is not required for a finding of obviousness; rather, only a reasonable expectation is needed. *In re O'Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988).

V. TEVA'S GALANTAMINE TABLETS WILL NOT INFRINGE ANY VALID OR ENFORCEABLE CLAIM OF U.S. PATENT NOS. 4,663,318, 6,099,863 AND 6,358,527

A. Teva's Galantamine Tablets Will Not Infringe Any Valid Claim Of The '318 Patent

Claims 1, 4 and 5

Claim 1 of the '318 patent reads as follows:

> 1. A method of treating Alzheimer's disease and related dementias which comprises administering to a patient suffering from such a disease a therapeutically effective amount of galanthamine or a pharmaceutically-acceptable acid addition salt thereof.

Independent claim 1, as properly construed, is invalid under 35 U.S.C. § 102(b) as anticipated by P.A. Bhasker, *Medical Management of Dementia*, THE ANTISEPTIC, Vol. 71, No. 1, pp. 45-47 (1974) ("the Bhasker Article") because the Bhasker Article (1) was published in 1974, making it prior art to the '318 patent under 35 U.S.C. § 102; and (2) discloses each and every element of claim 1 of the '318 patent.

The Bhasker Article discloses administering to patients small daily doses of cholinesterase inhibitors, such as galantamine, as a treatment for dementia. Thus, the Bhasker Article discloses administering a therapeutically effective amount of galantamine. The article points to categories of dementia where there is a progressive fallout of neurons and the course of the illness is rapidly downhill. Alzheimer's disease falls under this category.

In addition, the Bhasker Article renders claims 1, 4 and 5 of the '318 patent invalid under 35 U.S.C. § 103 because they would have been obvious to one of ordinary skill in the art at the time of the invention. It was known at the time of the invention that galantamine was a pharmaceutical compound that could be administered in any convenient chemical or physical form. The oral dosages recited in dependent claims 4 and 5 are not disclosed to provide any unexpected results. In light of the teachings in the Bhasker Article disclosure, these dosages would have been the obvious result of routine dose range testing.

Moreover, claims 1, 4 and 5 of the '318 patent are invalid under 35 U.S.C. § 103 because they are obvious in view of the following prior art: the Bhasker Article; Gopel et al., (1971)[3]; Cozanitis (1978)[4]; C.M. Smith et al. (1979)[5]; Mohs et al. (1985)[6]; Mohs et al. (1985)[7];

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[3] Gopel et al., *Erfahrungen mit nivalin in der neurologixhen therapie*, PSYCHIAT. NEUROL. MED. PSYCHOL., 23:712-18 (1971) (teaches galantamine is comparable in pharmacological effect to prostigmine and pyridostigmine).

Haroutunian et al. (1985)[8]; Davis et al. (1983)[9]; Levy et al. (1982)[10]; Ilyutchenok and Yeliseyeva (1972)[11]; Ilyutchenok (1982)[12]; Krauz et al. (1982)[13]; Plaitakis and Duvoisin (1983)[14]; Bretangne et al. (1965)[15]; Milbled et al. (1966)[16]; Ilyutchenok et al. (1968)[17];

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[4] Cozanitis, *L'hydrobromide de Galanthamine: Unsubstitut du Sulfate D'eserine (Physostigmine) Pour le Traitement des Effects Cerebraux des Substances Anti-Cholinergiques*, NOUV. PRESSE MED., 7(45):4152 (1978) (teaches galantamine hydrobromide is a substitute for physostigmine in treating cerebral diseases caused by anti-cholinergic substances and the authors suppose that galantamine would even be a better cholinesterase inhibitor than physostigmine because of its prolonged action).

[5] C.M. Smith et al., *Physostigmine in Alzheimer's Disease*, THE LANCET, p. 42 (6 January 1979) (discloses that the anti-cholinesterase drug physostigmine exhibits a positive effect in the treatment of Alzheimer's disease even in a fairly advanced stage of the disease).

[6] Mohs et al., *Clinical Studies of the Cholinergic Deficit in Alzheimer's Disease*, J. AM. GERIATRIC SOC., 33:749 (1985) (cites the need for the development of cholinomimetics other than physostigmine that are safe, long acting and beneficial in the great majority of patients).

[7] Mohs et al., *Oral Physostigmine Treatment of Patients With Alzheimer's Disease*, AM. J. PSYCHIATRY, 142:28-33 (1985) (states that there is a need to develop safer and more long-acting drugs which increase cholinergic activity, either by directly affecting receptors by inhibiting cholinesterase, or by stimulating presynaptic activity).

[8] Haroutunian et al., *Cholinergic Modulation of Memory in Rats*, PSYCHOPHARMACOLOGY, 87:266-71 (1985) (states that it may be possible to use agents similar to physostigmine in the treatment of memory disorders such as those characteristic of Alzheimer's disease).

[9] Davis et al., *Oral Physostigmine in Alzheimer's Disease*, PSYCHOPHARMACOLOGY BULLETIN, 19(2):451-53 (1983) (suggests that acetylcholinesterase inhibitors show more promise as a treatment strategy in Alzheimer's than other cholinergic treatments; states that "trials of pharmacologic agents [such as acetylcholinesterase inhibitors] that enhance cholinergic activity should be aggressively pursued, as they offer a rational treatment strategy based on observed neurochemical deficits").

[10] Levy et al., *Research Subject Recruitment for Gerontological Studies of Pharmacological Agents*, NEUROBIOL. AGING, 3(2):105-10 (1982) (points to benefits of using cholinesterase inhibitors to enhance memory and other aspects of cognition, for brief periods, in patients with Alzheimer's disease).

[11] Ilyutchenok and Yeliseyeva, *Cholinergic Mechanisms of Memory: Analysis of Amnesic Effect of Anticholinergic Drugs*, INTERNATIONAL JOURNAL OF PSYCHOBIOLOGY, 2(3):177-92 (1972) (demonstrated that galantamine reverses the memory impairing effects of cholinergic blockade; thus if memory improves with galantamine following pharmacologic impairment, it would be obvious to try galantamine to reverse pathological memory loss wherein cholinergic neurons are implicated).

[12] Ilyutchenok, *Pharmacological Aspects of Memory Neurochemical Regulation*, BULGARIAN ACADEMY OF SCIENCES: ACTA PHYSIOLOGICA ET PHARMACOLOGICA BULGARICA, 8(1-2):43-49 (1982) (galantamine affects cholinergic neurons in areas specific for, or at least implicated in memory and memory loss).

[13] Krauz et al., *Role of Cholinergic Mechanisms in ATPase Activity and Glycolysis Intensity Regulation in the Rat Neocortex, Hippocampus and Truncus Cerebri*, FARMAKOLOGIA I TOKSIKOLOGIA, 1:22-26 (1982) (galantamine affects cholinergic neurons in areas specific for, or at least implicated in memory and memory loss).

[14] Plaitakis and Duvoisin, *Homer's Moly Identified as Galanthus Nivalis L.: Physiologic Antidote to Stramonium Poisoning*, CLINICAL NEUROPHARMACOLOGY, 6(1):1-5 (1983) (describing well known pharmaceutical effects of galantamine).

Ilyutchenok (1968)[18]; Cozanitis et al. (1971)[19]; Davis et al. (1978)[20]; Davis and Mohs (1982)[21]; Peters and Levin (1979)[22] and Pernov (1961)[23]. Specifically, for claim 1, prior to the effective date of the '318 patent, 15 January 1986, acetylcholinesterase inhibitors were known to be effective in conditions of memory loss.[24] Both physostigmine and galantamine were known to be acetylcholinesterase inhibitors[25] and physostigmine was known to be effective in treating Alzheimer's disease.[26] In addition, galantamine was known to have advantages over physostigmine as an acetylcholinesterase inhibitor.[27] Based on this knowledge, it would have been obvious to one skilled in the art to use galantamine as a replacement for physostigmine on patients suffering from Alzheimer's disease and related dementia by administering galantamine with a reasonable expectation of success. *See In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) ("Obviousness does not require absolute predictability. Only a reasonable expectation that the beneficial result will be achieved is necessary to show obviousness."). Accordingly, claims 1, 4 and 5 of the '318 patent are invalid under 35 U.S.C. § 103 because they are obvious in view of the prior art.

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15 Bretagne et al., *Essais Cliniques en Anesthesiology d'un Nouvel Anticholinesterasique la Galanthamine*, ANESTHENE ANALGESIC, 1:285-92 (1965) (reports the clinical effects of galantamine (10-25 mg IV) in anesthesia in humans).

16 Milbled et al., *Sur l'action Centrale de la Galanthamine*, C.R. Soc. Biol. 16:2059-90 (1966) (describes the central nervous system effects of galantamine in rats).

17 Ilyutchenok et al., *Comparison of the Effects Produced by Anticholinergic and Anticholinesterase Substances Upon Induced Potential of the Cerebral Cortex*, FARMAKOLOGIA I TOKSIKOLOGIA, 4:413-14 (1968) (comparison of the effects of galantamine and physostigmine in anticholinesterase activity in cats).

18 Ilyutchenok, *Cholinergic Brain Mechanisms and Behaviour*, PROG. BRAIN. RES., 28:134-48 (1968) (discusses the effects of galantamine on brain cholinergic parameters).

19 Cozanitis et al., (1971) (compare the effects of galantamine and atropine/neostigmine in human volunteers).

20 Davis et al. (1971), *Physostigmine: Improvement of Long-Term Memory Processes in Normal Humans*, SCIENCE 201:272-74 (1978)

21 Davis and Mohs, *Enhancement of Memory Processes in Alzheimer's Disease with Multiple-Dose Intravenous Physostigmine*, AM. J. PSYCHIATRY 134:1421-24 (1982).

22 Peters and Levin, *Effect of physostigmine and Lecithin on Memory in Alzheimer's Disease*, ANN. NEURAL 6:219-21 (1979).

23 Pernov, *Das Nivalin und seine Heilwirkung bei Erkrankungen des Nervensystems*, PSYCHIATRIC NEUROL MED. PSYCHOL. 13:416-20 (1961).

24 *See, e.g.*, Davis et al. (1978); Haroutunion et al. (1985).

25 *See, e.g.*, Gopel et al. (1971).

26 *See, e.g.*, Davis and Mohs (1982); Peters and Levin (1979).

27 *See, e.g.*, Pernov (1961).

Claims 2, 3, 6 and 7

Teva's Galantamine Tablets do not infringe claims 2, 3, 6 and 7 of the '318 patent. Claims 2, 3 and 6 require parenteral administration of galanthamine and Claim 7 requires intracerebroventricular administration of galanthamine via an implanted reservoir. Teva's Galantamine Tablets require oral administration. Accordingly, Teva's Galantamine Tablets do not infringe claims 2, 3, 6 and 7, either literally or under the doctrine of equivalents.

B. Teva's Galantamine Tablets Will Not Infringe Any Claim Of The '863 Patent

Claim 1

Claim 1 of the '863 patent reads as follows:

> 1. A tablet comprising as an active ingredient a therapeutically effective amount of galanthamine hydrobromide (1:1) and a pharmaceutically acceptable carrier, wherein said carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.

Independent claim 1 requires "a pharmaceutically acceptable carrier, wherein said carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent . . . ." Teva's Galantamine Tablets do not contain a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25). Teva's Galantamine Tablets contain a mixture of spray-dried lactose and microcrystalline cellulose in an approximate weight ratio of 1:1. Accordingly, Teva's Galantamine Tablets do not literally infringe claim 1 of the '863 patent.

Teva's Galantamine Tablets do not infringe claim 1 of the '863 patent under the doctrine of equivalents. The written description of the '863 patent disclaims a scope that would cover a mixture of spray-dried lactose and microcrystalline cellulose in a 1:1 weight ratio. Expanding claim 1 to encompass a mixture of spray-dried lactose and microcrystalline cellulose in an approximate weight ratio of 1:1 would be an impermissible embrace of structure that is specifically excluded from the scope of the claims. *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1345-46 (Fed. Cir. 2001). Further, the difference between a mixture of spray-dried lactose and microcrystalline cellulose in an approximate 1:1 weight ratio, and a spray-dried mixture of lactose monohydrate and microcrystalline cellulose in a 75:25 weight ratio is not insubstantial. *See Abbott Labs. v. Novopharm Ltd.*, 323 F.3d 1324, 1329 (Fed. Cir. 2003). Accordingly, the manufacture, use, sale or offer for sale within the United States, or importation into the United States, of Teva's Galantamine Tablets would not infringe claim 1 of the '863 patent, either literally or under the doctrine of equivalents.

Claims 2–10

Claims 2-10 ultimately depend on claim 1. If an accused product does not infringe an independent claim, it does not infringe any claim dependent thereon. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989). Accordingly, for at least the reasons stated with regard to claim 1, Teva's Galantamine Tablets do not infringe claims 2–10, either literally or under the doctrine of equivalents.

C. Teva's Galantamine Tablets Will Not Infringe Any Claim Of The '527 Patent

Claim 1

Claim 1 of the '527 patent reads as follows:

> 1. A method of treating a disorder selected from dementia, mania or nicotine dependence in a patient in need thereof comprising administering to the patient a tablet comprising as an active ingredient a therapeutically effective amount of galanthamine hydrobromide (1:1) and a pharmaceutically acceptable carrier, wherein said carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.

Independent claim 1 requires a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant. Teva's Galantamine Tablets do not contain a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25). Teva's Galantamine Tablets contain a mixture of spray-dried lactose and microcrystalline cellulose in an approximate weight ratio of 1:1. Accordingly, Teva's Galantamine Tablets do not literally infringe claim 1 of the '527 patent.

Teva's Galantamine Tablets do not infringe claim 1 of the '527 patent under the doctrine of equivalents. The written description of the '527 patent disclaims a scope that would cover a mixture of spray-dried lactose and microcrystalline cellulose in a 1:1 weight ratio. Expanding claim 1 to encompass a mixture of spray-dried lactose and microcrystalline cellulose in an approximate weight ratio of 1:1 would be an impermissible embrace of structure that is specifically excluded from the scope of the claims. *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1345-46 (Fed. Cir. 2001). Further, the difference between a mixture of spray-dried lactose and microcrystalline cellulose in an approximate 1:1 weight ratio, and a spray-dried mixture of lactose monohydrate and microcrystalline cellulose in a 75:25 weight ratio is not insubstantial. *See Abbott Labs. v. Novopharm Ltd.*, 323 F.3d 1324, 1329 (Fed. Cir. 2003). Accordingly, the manufacture, use, sale or offer for sale within the

United States, or importation into the United States, of Teva's Galantamine Tablets would not infringe claim 1 of the '527 patent, either literally or under the doctrine of equivalents.

Claims 2–5

Claims 2-5 ultimately depend upon claim 1. Accordingly, Teva's Galantamine Tablets cannot infringe claims 2–5, either literally or under the doctrine of equivalents. *Wahpeton Canvas Co.*, 870 F.2d at 1552 n.9.

Claim 6

Claim 6 reads as follows:

> 6. A fast-dissolving galanthamine hydrobromide (1:1) tablet made by (i) dry blending the active ingredient, an insoluble or poorly soluble cross-linked polymer disintegrant and an optional glidant with a diluent comprising a spray dried mixture of lactose monohydrate and microcrystalline cellulose (75:25); (ii) optionally mixing a lubricant with the mixture obtained in step (i); (iii) compressing the mixture obtained in step (i) or in step (ii) in the dry state into a tablet; and (iv) optionally film-coating the tablet obtained in step (iii).

Like claim 1, independent claim 6 requires a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant. Therefore, for the same reasons given above for claim 1, Teva's Galantamine Tablets would not infringe claim 6 of the '527 patent, either literally or under the doctrine of equivalents.

V. CONCLUSION

For the foregoing reasons, all of the claims of the '318, '863 and '527 patent are invalid or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use or sale of Teva's Galantamine Tablets for which this detailed statement is submitted. Teva USA reserves the right to assert additional grounds, reasons or authorities that any or all of the claims of the '318, '863 and '527 patents are invalid, unenforceable or not infringed.

CERTIFICATE OF SERVICE

I hereby certify that on the 21st day of February, 2006, the attached **NOTICE OF DEPOSITION UNDER FED. R. CIV. P. 30(b)(6) TO TEVA PHARMACEUTICALS INDUSTRIES, LTD. AND TEVA PHARMACEUTICALS USA** was served upon the below-named counsel of record at the address and in the manner indicated:

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